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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,858	GISH ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-70 are pending and are under prosecution.

It is noted that it seems that by typographic error, claim 70 depends on claim 59. Claim 70 seems to depends on claim 69 rather than on claim 59, because claim 70 recites the step of determining the level of expression in the presence or absence of a drug candidate, which seems to belong the step of the method of claim 69, and not of the method of claim 59.

For the purpose of compact prosecution, it is assumed that claim 70 depends on claim 69. Appropriate correction is required.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group A. Claims 1-12, 52-67, drawn to a method for detecting or quantifying a prostate-cancer associated transcript, comprising detecting a polynucleotide sequence or a combination of polynucleotide sequences shown in tables 1-16, classified in class 435, subclass 6. A method detecting each of 8014 polynucleotide sequences shown in tables 1-16, or each combination of the polynucleotide sequences shown in tables 1-16 constitutes a single, distinct invention.

Group B. Claims 13-15, drawn to a method for monitoring the efficacy of a therapeutic treatment of prostate cancer, comprising determining the level of a polynucleotide sequence shown in tables 1-16, classified in class 435, subclass 6. A method detecting each of 8014 polynucleotide sequences shown in tables 1-16 constitutes a single, distinct invention.

Group C. Claims 16-18, drawn to a method for monitoring the efficacy of a therapeutic treatment of prostate cancer, comprising determining the level of an antibody that specifically binds to a polypeptide encoded by a polynucleotide sequence shown in tables 1-16, classified in class 435, subclass 7.1. A method detecting each antibody that specifically binds to each polypeptide encoded by each of 8014 polynucleotide sequences shown in tables 1-16 constitutes a single, distinct invention.

Group D. Claims 18-21, drawn to a method for monitoring the efficacy of a therapeutic treatment of prostate cancer, comprising determining the level of a polypeptide encoded by a polynucleotide sequence shown in tables 1-16, classified in class 435, subclass 7.1. A method detecting each polypeptide encoded by each of 8014 polynucleotide sequences shown in tables 1-16 constitutes a single, distinct invention.

Group E. Claims 22-26, drawn to nucleic acid molecules consisting of polynucleotide sequences shown in tables 1-16, classified in class 536, subclass 23.1. Each of 8014 polynucleotide sequences shown in tables 1-16 constitutes a single, distinct invention.

Group F. Claim 27, drawn to polypeptides encoded by nucleic acid molecules consisting of polynucleotide sequences shown in tables 1-16, classified in class 530, subclass 350. Each polypeptide encoded by each of 8014 polynucleotide sequences shown in tables 1-16 constitutes a single, distinct invention.

Group G. Claims 28-33, drawn to antibodies that specifically bind to polypeptides encoded by nucleic acid molecules consisting of polynucleotide sequences shown in tables 1-16, classified in class 530, subclass 387.1. Each antibody

that specifically binds to each polypeptide encoded by each of 8014 polynucleotide sequences shown in tables 1-16 constitutes a single, distinct invention.

Group H. Claims 34-36, drawn to a method for detecting a prostate cancer cell, comprising detecting a polypeptide encoded by a polynucleotide sequence shown in tables 1-16, classified in class 435, subclass 7.1. A method detecting each polypeptide encoded by each of 8014 polynucleotide sequences shown in tables 1-16 constitutes a single, distinct invention.

Group I. Claim 37, drawn to a method for detecting antibodies specific to prostate cancer, comprising contacting a sample with a polypeptide encoded by a nucleic acid shown in tables 1-16, classified in class 435, subclass 7.1. A method detecting an antibody that binds to each polypeptide encoded by each of 8014 polynucleotide sequences shown in tables 1-16 constitutes a single, distinct invention.

Group J. Claims 38-43, 69-70, drawn to a method for identifying a compound that modulates a prostate-cancer associated polypeptide, comprising determining the functional effect of the compound upon the polypeptide encoded by a polynucleotide shown in tables 1-16, classified in class 435, subclass 7.1. A method determining the functional effect of a compound upon each of the polypeptide encoded by each of 8014 polynucleotides shown in tables 1-16 constitutes a single, distinct invention.

Group K. Claims 44-46, drawn to a method for treating prostate cancer, comprising administering a compound that effects the function of a polypeptide encoded by a polynucleotide shown in tables 1-16, classified in class 424, subclass 130.1. A method using a compound that effects the function of each polypeptide encoded by

each of 8014 polynucleotides shown in tables 1-16 constitutes a single, distinct invention.

Group L. Claims 47-49, 69-70, drawn to a drug screening assay, for a test compound that modulates the mRNA level of expression of a polynucleotide shown in Tables 1-16, classified in class 435, subclass 6. A screening assay for a test compound that modulates the mRNA level of expression of each of 8014 polynucleotides shown in Tables 1-16 constitutes a single, distinct invention.

Group M. Claim 50, drawn to a method for treating prostate cancer, comprising administering a compound that modulates the mRNA level of expression of a polynucleotide shown in Tables 1-16, classified in class 514, subclass 44. A method using a compound that modulates the mRNA level of expression of each of 8014 polynucleotides shown in Tables 1-16 constitutes a single, distinct invention.

Group N. Claim 51, drawn to a pharmaceutical composition, comprising a compound that modulates the mRNA level of expression of a polynucleotide shown in Tables 1-16, classified in class 536, subclass 23.1. A compound that modulates the mRNA level of expression of each of 8014 polynucleotides shown in Tables 1-16 constitutes a single, distinct invention.

Group O. Claim 68, drawn to a biochip comprising a plurality of polynucleotidess shown in tables 1-16, classified in class 536, subclass 23.1. A biochip comprising each combination of polynucleotides shown in tables 1-16 constitutes a single, distinct invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups A-D, H-N are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions of groups E-G, N-O as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

The inventions of Groups (A, B) and E are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polynucleotide product as claimed can be used in a materially different process such as for making a vector.

The inventions of Groups (C, D, H, I) and (F, G) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as for making antibody, and the antibody product can be used for making affinity chromatography.

The inventions of Groups J and F are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polypeptide product as claimed can be used in a materially different process such as for making antibody.

The inventions of Groups L and E are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the polynucleotide product as claimed can be used in a materially different process such as for making a vector.

The inventions of Groups M and N are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the compound that modulates the level of the polynucleotide as claimed, such as an antisense can be used in a materially different process such as for detecting the polynucleotide.

The inventions of Groups E and (C, D, H, I, J, K, M) are not at all related because the methods of groups C-K, M do not use the polynucleotide of group E.

The inventions of Groups F, G and (A-B, K-M) are not at all related because the methods of groups A-B, K-M do not use the polypeptide of group F, or the antibody of group G.

The inventions of Groups N and (A-D, H, I, J, K, L) are not at all related because the methods of groups A-D, H, I, J, K, L do not use the modulating compound of group N.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement could be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CHRISTINA CHAN can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

May 30, 2004